Reduces the Risk of Air Embolism\textsuperscript{1,}\textsuperscript{*}

\textbf{In-Service Training}

\textsuperscript{1} Persson and van der Linden. Journal of Cardiothoracic and Vascular Anesthesia 2003;17;329-35.

*Compared to open-ended tubing CO\textsubscript{2} delivery in an in vitro model.
Intended Audience

• CV Surgeons
• Perfusionists
• CV Anesthesiologists
• CV OR Team
Clinical Challenge: Preventing Air Emboli

Preventing Air Emboli During Open Heart Surgery

• Air enters the heart during open-heart surgery and/or when the lung veins and the great vessels are opened

• Air is trapped at the highest level in each cavity of the left side of the heart (Fig. 1)

• Air bubbles are ejected into the aorta during weaning from Cardio Pulmonary Bypass (CPB)

• Arterial air emboli can occur (Fig. 2)

Common methods used to prevent air embolism at the end of open heart surgical procedures:

- CO₂ delivered through open-ended tubing\(^1\)\(^2\) CO₂ has been used for de-airing since 1953 because of two important properties: CO₂ is heavier than air and it dissolves very quickly.

- Venting of air from the ascending aorta by insertion of a needle at the highest portion\(^1\)\(^2\)

- TEE (Trans Esophagus Echo) guided surgical maneuvers, such as shaking of the heart, suctioning through a needle inserted in the left ventricle\(^1\)\(^2\)

- Trendelenburg maneuver (head down; Fig. 1)\(^2\)

- Hyperinflation of the lungs\(^2\)

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2. Survey Results from CryoLife market research of US Perfusionists (n=6), Boston, MA, April 30, 2017.
Challenge: Open-ended Tubing and Air Bubbles

Open-ended tubing is inadequate due to “high outflow velocities” and “the air turbulence the jet generates” which causes CO₂ to exit the cavity.¹

Open-end Tubing Challenges:

• Small open-ended tubing = high velocity and turbulence which causes CO₂ to exit cavity¹
• Risk for air embolism¹
• Risk for infections³,⁴

2. Svernarud et al. Circulation 2004;109:1127-32. Median number of microemboli after discontinuation of cardiopulmonary bypass was zero at 19 minutes with Open-ended Tubing in 3 areas of interest (left ventricle, left atrium, and proximal part of ascending aorta taken together shown by TEE).
Solution: CarbonAid and CarbonMini CO₂ Diffuser

CarbonAid and CarbonMini CO₂ Diffuser devices have been designed to:

• Reduce the Risk of Air Embolism¹,*
  • By replacing air with >99% CO₂ (p<0.001)¹,*

CarbonAid and CarbonMini CO₂ Diffuser devices replace air with CO₂ which:

• Significantly Reduces Time for Microemboli to Disappear
  • ~12 minutes (p≤0.01)²,³

• May Prevent Infections
  • By creating a >99% CO₂ bacteriostatic atmosphere⁴,⁵

*Compared to open-ended tubing CO₂ delivery in an in vitro model.

3. Figure 2 in Svernarud et al., median number of microemboli after discontinuation of cardiopulmonary bypass was 0 with CarbonAid at 8 minutes vs. 20 minutes with Open-ended Tubing in 3 areas of interest (left ventricle, left atrium, and proximal part of ascending aorta taken together shown by TEE).
“Conventional open-ended tubes provided a poor and varying de-airing of the wound cavity model (18%-96% remaining air) because of CO₂ jets with calculated velocities between 1.3 and 34 meter/second […]”

The [CarbonAid] gas diffuser provided an almost complete de-airing of the model (0.2% remaining air) at flows of 5 to 10 L/min. This was a result of a uniform distribution of CO₂ with calculated velocities of about 0.1 meter/second.”¹

**Conclusion:** “These data imply that de-airing of a cardiothoracic wound by CO\(_2\) insufflation depends on flow and outflow velocity. To compensate for diffusion with ambient air, the CO\(_2\) flow should be > 5 L/min, and the outflow velocity should be about 0.1 m/s or less to avoid turbulence in the wound. This is only attainable with a [CarbonAid CO\(_2\)] gas diffuser.”

The mean air content in % (n=80) at half the depth of the model plotted versus the calculated outflow velocity (m/s) of the 2.5 mm tube, the 1/4-in tube, and the gas diffuser at CO\(_2\) flows of 2.5, 5, 7.5, and 10 L/min. The 4 values of the gas diffuser are located close to the origin of coordinates because of low air contents caused by low outflow velocities. The curve represents an exponential regression of the data.

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Indication for Use: CarbonAid and CarbonMini CO₂ Diffusers

To be used during open heart surgery procedures for insufflation of CO₂ into the thoracic cavity to reduce the risk of air embolism.¹ ² Including the following:

• Valve surgery
• Atrial/ventricular septum defect closure
• Left ventricular reconstruction
• Aortic surgery
• Single clamp coronary surgery
• Insertion of ECMO through sternotomy
• Insertion of LVAD
• Heart transplantation

¹ Instructions for Use CarbonAid CO₂ Diffuser. ² Instructions for Use CarbonMini CO₂ Diffuser.
CarbonAid and CarbonMini CO₂ Diffuser Sizes

CarbonAid CO₂ Diffuser
For larger wound openings
>8 cm in diameter¹

CarbonMini CO₂ Diffuser
For smaller wound openings
<3–8 cm in diameter²

¹. Instructions for Use CarbonAid CO₂ Diffuser.
². Instructions for Use CarbonMini CO₂ Diffuser.
In-Service Training

This in-service training is intended for general instruction of CarbonAid and CarbonMini CO$_2$ Diffusers.

Variations in use may occur in specific procedures due to individual techniques and patient conditions.
Step 1:

• CO₂ Source: Determine in advance how CO₂ gas is delivered in the OR. It may be from a central source or a tank.

• Secure a CO₂ gas source with the capacity to deliver CO₂ flow via a CO₂ flow meter during the estimated time for procedure. Approximately 1 kg CO₂/hour is consumed when the flow is set for 10 liter/minute.

• If a tank is being used, confirm that a backup tank is available for lengthy or concomitant cases.

• Connect tubing to CO₂ source. The gas source must include a pressure regulator and a CO₂ flow meter.

1. Instructions for Use CarbonAid CO₂ Diffuser.
2. Instructions for Use CarbonMini CO₂ Diffuser.
Flow Meter and Pressure Regulator\textsuperscript{1,2}

Step 2:

- The CO\textsubscript{2} flow meter shall contain or be connected to a pressure regulator.
- The service pressure for the CO\textsubscript{2} gas is set between 3.5-4.5 bar (50-65 psi or 350-450 kpa).
- The set gas flow should continue until the closure of the heart, the lung veins, and the great vessels is completed.

\textsuperscript{1} Instructions for Use CarbonAid CO\textsubscript{2} Diffuser.
\textsuperscript{2} Instructions for Use CarbonMini CO\textsubscript{2} Diffuser.
Device Selection and Flow Rate

Step 3:
• Select the appropriate product and recommended flow rate

<table>
<thead>
<tr>
<th>Diameter of surgical wound opening</th>
<th>CO₂ flow Recommended</th>
<th>Recommended Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;3 cm</td>
<td>3 L/Min</td>
<td>CarbonMini¹</td>
</tr>
<tr>
<td>3-4 cm</td>
<td>5 L/Min</td>
<td>CarbonMini¹</td>
</tr>
<tr>
<td>5-8 cm</td>
<td>8 L/Min</td>
<td>CarbonMini¹</td>
</tr>
<tr>
<td>&gt;8 cm</td>
<td>10 L/Min</td>
<td>CarbonAid²</td>
</tr>
</tbody>
</table>

1. Instructions for Use CarbonMini CO₂ Diffuser.
2. Instructions for Use CarbonAid CO₂ Diffuser.
Step 4:

Open Sternotomy CarbonAid Positioning:
Place the foam tip at the caudal end of the wound. Bend the thin tubing so the foam tip is placed approximately 2 inches (5 cm) below the skin surface.

Minimally Invasive CarbonMini Positioning:
Place the foam tip at the caudal end of the wound. Bend the thin tubing so the foam tip is placed approximately 1-2 inches (2-4 cm) below the skin surface.

1. Instructions for Use CarbonAid CO₂ Diffuser.
2. Instructions for Use CarbonMini CO₂ Diffuser.
Positioning (continued)

Step 4 (continued):
CarbonMini positioning during minimally invasive cases is surgeon preference. Field experience has reported placement options may be:

• Placement in MI cavity or
• Placement in a specially created port just superior of the incision site.
Step 5:
Immobilize the tubing per surgeon preferred method near the caudal end of the wound.
Attachment methods may include:
• Sutures or
• Adhesive sterile tape

1. Instructions for Use CarbonAid CO₂ Diffuser.
2. Instructions for Use CarbonMini CO₂ Diffuser.
Foam Tip Positioning\textsuperscript{1,2}

Step 6:

- The foam tip should be positioned a few centimeters below skin surface.
- Avoid submerging the foam tip in fluid.*
- If the foam tip gets soaked with fluid its full function can quickly be restored by squeezing the tip with two fingers to remove the trapped fluid.

*If the foam tip is completely covered in fluid, CarbonAid and CarbonMini may not be able to deliver CO\textsubscript{2} gas properly.

1. Instructions for Use CarbonAid CO\textsubscript{2} Diffuser.
2. Instructions for Use CarbonMini CO\textsubscript{2} Diffuser.
Device Selection and Flow Rate\textsuperscript{1,2}

Step 7:

• Connect tubing to CO\textsubscript{2} Source. The gas source must include a pressure regulator and a CO\textsubscript{2} flow meter.

• Start the recommended CO\textsubscript{2} gas flow before opening of the heart, the lung veins and/or the great vessels to ensure saturated CO\textsubscript{2} atmosphere as follows:
  
  – CarbonAid: CO\textsubscript{2} gas flow should be started at least \textbf{one (1) minute} before the heart, the lung veins and/or the great vessels are opened.\textsuperscript{1}
  
  – CarbonMini: CO\textsubscript{2} gas flow should be started at least \textbf{two (2) minutes} before the heart, the lung veins and/or the great vessels are opened.\textsuperscript{2}

\textsuperscript{1} Instructions for Use CarbonAid CO\textsubscript{2} Diffuser.
\textsuperscript{2} Instructions for Use CarbonMini CO\textsubscript{2} Diffuser.
Step 8:
Use intermittent suction within the cavity by having the suctioning device outside of the cavity when not in use.

If a suction device is used in the cavity, avoid suctioning when no fluid is present and try to minimize the suction rate to avoid depletion of CO$_2$.

This is to be coordinated with the perfusionist.

Step 9:
Inform the CV anesthesiologist that at the end of surgery, CO₂ bubbles often show up on echo and is often confused with air bubbles.

The difference is: CO₂ bubbles will dissipate almost immediately, unlike oxygen bubbles which take more time to be dissolved, sometimes 15 to 20 minutes.¹

¹ Cardia Innovation
Device Removal

Step 10:
At completion of a procedure, gently remove the CarbonAid or CarbonMini CO₂ Diffuser.